- - HBcAg has been demonstrated to be a very good carrier. HBcAg is a highly immunogenic antigen in human and animal models. HBcAg directly activates B cells and generates strong T cell responses. Furthermore, the efficient processing and presentation of HBcAg by the antigen presenting cells makes it an ideal carrier molecule. Hence a large number of epitopes have been chemically linked or genetically fused to the HBcAg molecule to successfully increase their immunogenicity. Bacterial expression vectors have been designed to enable the insertion of heterologous B cell epitopes in different positions inside the particles of HBcAg and the efficient purification of hybrid particles. - -

b2

At page 5, after line 22 and before the section entitled "**Detailed description of the invention**" please insert the following:

- - **Summary of the invention**

Sub. C1 D1

The present invention provides a vaccine formulation suitable for mucosal administration, the vaccine includes a mixture of a virus-like particle (VLP) comprising a surface antigen from a virus, and a non-living vaccine antigen, the surface antigen having an adjuvant effect on said vaccine antigen. Each vaccine dose includes up to about 1 milligram each of the surface antigen and vaccine antigen. The vaccine formulation may include one or more of the following: a preservative, a stabilizer and a second vaccine antigen.

b3

In a particular embodiment the surface antigen is Hepatitis B virus surface antigen (HBsAg). The vaccine antigen may an antigen of a viral nucleocapsid, such as the nucleocapsid

b3 (cont)

antigen of Hepatitis B virus, the nucleocapsid antigen of Human papilloma-virus, or the nucleocapsid antigen of Hepatitis C virus.

Brief description of the figures

Figure 1. Three doses schedule (days 0, 14 and 28). Extraction was performed on day 42. Groups 1 and 2 were inoculated with 50 μL through the nasal route. Group 3 was inoculated subcutaneously with 100 μL.

Figure 2. Two doses schedule (days 0 and 14). Extraction was performed on day 21. Groups 1, 2 and 3 were inoculated with 50 μL through the nasal route. Group 4 was inoculated subcutaneously with 100 μL.

Figure 3. Three doses schedule (days 0, 14 and 28). Extraction was performed on day 26. Groups 1, 2, 3, 4 and 5 were inoculated through the nasal route. Group 6 was inoculated intramuscularly with 100 μL.

Figure 4. Two doses schedule (days 0 and 14). Extraction was performed on day 26. All groups were inoculated nasally with 50 μL. The composition of experimental groups is shown in the table added to the figure.

Figure 5. Three doses schedule (days 0, 14 and 28). Extraction was performed on day 42. Groups 1,2 and 3 were inoculated with 50 μL through the nasal route. - -